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OCHAMPUS 6010.47-M
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PUBLICATIONS SYSTEM CHANGE TRANSMITTAL FOR TRICARE/CHAMPUS POLICY MANUAL

THE DIRECTOR, OCHAMPUS, HAS AUTHORIZED THE FOLLOWING ADDITION(S)/REVISION(S) TO THE TRICARE/CHAMPUS POLICY MANUAL

REVISION(S)

CHAPTER(S): 3 SECTION(S): 6.1

REMOVE PAGE(S):

CHAPTER 3, SECTION 6.1, PAGES 1-8.

INSERT: ATTACHED ADDITIONAL/REPLACEMENT PAGE(S):

CHAPTER 3, SECTION 6.1, PAGES 1-8.

SUMMARY OF ADDITIONS/REVISIONS: This change implements the national Specialized Treatment Service (STS) for allogeneic bone marrow transplants.

EFFECTIVE DATE AND IMPLEMENTATION: Upon direction of the Contracting Officer.

THIS CHANGE IS MADE IN CONJUNCTION WITH OPERATIONS MANUAL CHANGE NO.100, COM-FI NO.97, AND ADP MANUAL CHANGE NO.62.

Sheila H. Sparkman
Director, Program Development and Evaluation

ATTACHMENT(S): 8 PAGE(S)
DISTRIBUTION: 6010.47-M

WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT

Subject: HIGH DOSE CHEMOTHERAPY AND STEM CELL TRANSPLANTATION	Chapter: 3
Authority: DoD 6010.8-R, Chapter 4, E.5.	Section: 6.1
	Issue Date: November 1, 1983

PROCEDURE CODE RANGE

38230, 38240, 38241

DESCRIPTION

A. TRICARE/CHAMPUS defines high dose chemotherapy (HDC) as the use of cytotoxic therapeutic agents (that are otherwise approved by the FDA for general use in humans) in dosages and/or frequencies of dosage that exceed the FDA labelling for the agent. HDC is generally considered when conventional regimens of chemotherapeutic agents have failed to arrest disease progression. One of the major adverse effects of HDC is that of bone marrow suppression, itself a potentially lethal process.

B. Stem cells are multipotential, blood-cell producing agents important in immune defenses against disease.

C. TRICARE/CHAMPUS defines stem cell "transplantation" or "rescue" as a technique for collecting stem cells from a donor (either from the bone marrow or from the bloodstream), preparing and storing the collected stem cells, then reinfusing the prepared stem cells into the bloodstream of a patient in the treatment of oncologic, hematologic or lymphoproliferative disease with curative potential. The goal of stem cell "transplantation" or "rescue" is to reverse the bone marrow suppression caused by either HDC or by a primary bone marrow disease process (e.g., aplastic anemia).

There are three general types of stem cell "transplantation" or "rescue":

1. Autologous bone marrow transplant (ABMT), where the patient is both donor and recipient of stem cells harvested from the bone marrow.

2. Peripheral stem cell therapy (PSCT), where the patient is both donor and receipient of stem cells harvested from the bloodstream using the apheresis process. This technique is generally reserved for those patients who have disease involvement of their bone marrow, making ABMT less satisfactory.

3. Allogeneic bone marrow transplantation (BMT), where stem cells from a histocompatible donor (other than the patient) are harvested, then later infused into the bloodstream of the patient. With BMT, the patient may have either a related or unrelated donor who has the same or closely matched human leukocyte antigen (HLA) typing necessary for successful transplantation.

POLICY

A. Preauthorized TRICARE/CHAMPUS benefits are allowed for HDC with ABMT or PSCT.

HIGH DOSE CHEMOTHERAPY AND STEM CELL TRANSPLANTATION	Chapter: 3
	Section: 6.1

1. TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the Health Care Finder (HCF) before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and HCF authorization, penalties will be administered according TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian reporters without the required PCM referral and HCF authorization, Managed Care Support (MCS) contractors shall reimburse charges for the services on a Point of Services basis. Special cost-sharing requirements apply to Point of Service claims. For specific information on Point of Service cost-shares and catastrophic cap calculations, see Chapter 12, Section 2.2, and Section 10.1, and Chapter 13, Section 14.1.

2. For Standard and Extra patients residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director, Health Care Finder, or other designated utilization staff.

3. For fiscal intermediaries, preauthorization authority is the responsibility of the TRICARE Medical Director.

B. Allogeneic Stem Cell Transplantation (Allogeneic Bone Marrow Transplantation).

1. Admissions on or after October 1, 1997. The Air Force Wilford Hall Medical Center (WHMC), Lackland AFB, Texas, is designated the national Specialized Treatment Service Facility (STSF) for allogeneic bone marrow transplantation. See OPM Part Two, Chapter 24 and COM-FI Part Two, Chapter 24.

a. For admissions on or after October 1, 1997, all beneficiaries who reside in the continental United States (i.e., 48 contiguous states and the District of Columbia) and are in need of an allogeneic stem cell transplantation, must be evaluated by WHMC before receiving an allogeneic stem cell transplantation (with or without HDC), except for those beneficiaries participating in DoD's cancer demonstration project (as provided in OPM Part Two, Chapter 20, Addendum C. or COM-FI Part Two, Chapter 20, Addendum C.).

b. If the allogeneic stem cell transplantation cannot be performed at WHMC an STSF NAS will be issued by WHMC, reference COM-FI Part Two, Chapter 24 and OPM Part Two, Chapter 24.

NOTE: *An STS NAS is not required for TRICARE Prime enrollees even when these beneficiaries use the Point of Service (POS) option. The enrollees are required to obtain authorization from the Health Care Finder. See OPM Part Two, Chapter 24.*

2. Admissions prior to October 1, 1997. Preauthorizations and initial management of all requests for allogeneic stem cell transplantations (with or without HDC) are provided by:

Wilford Hall Medical Center (WHMC)
Bone Marrow Transplantation Program
2200 Bergquist Drive, Suite 1
Lackland AFB, TX 78236-5300
Telephone: (210) 292-7080 or (210) 292-7391

TRICARE/CHAMPUS benefits for allogeneic stem cell transplantation will only be

allowed when WHMC has provided written authorization. (See also COM-FI Part Two, Chapter 20, Addendum A. and OPM Part Two, Chapter 20, Addendum A.)

C. The designated preauthorizing authority shall only use the criteria contained in this policy when preauthorizing HDC with ABMT or PSCT (with or without HDC), and allogeneic BMT (with or without HDC).

D. HDC with ABMT or PSCT is covered in the treatment of the following malignancies:

1. Non-Hodgkin's lymphoma, intermediate or high grade (see Exclusions for low grad lymphomas); and Hodgkin's disease when:

a. Conventional dose chemotherapy has failed; or

b. The patient has relapsed following a course of radiation therapy, and has also failed at least one course of conventional dose chemotherapy subsequent to the failed radiation therapy; and

c. In the case of ABMT, the patient has adequate marrow function and no evidence of marrow involvement with lymphoma.

NOTE: *For purposes of TRICARE/CHAMPUS coverage, mantle cell lymphomas will be considered as intermediate grade, non-Hodgkin's lymphomas.*

2. Neuroblastoma, Stage III or IV, when the patient is one for whom further treatment with a conventional dose therapy is not likely to achieve a durable remission.

3. Acute lymphocytic or nonlymphocytic leukemias;

4. Primitive neuroectodermal tumors (PNET), to include peripheral PNETs, provided that:

a. Standard dose chemotherapy has failed; and

b. In the case of ABMT, the patient has adequate marrow function with no evidence of tumor involvement in the marrow.

5. Gliofibromas (also known as desmoplastic astrocytoma; desmoplastic glioblastoma).

6. Glioblastoma multiforme.

7. Posterior fossa teratoid brain tumors.

8. Rhabdomyosarcoma and undifferentiated sarcomas when the medical record documents that the patient has failed the course of therapy recommended by the Intergroup Rhabdomyosarcoma Study.

9. Multiple myeloma.

10. Metastatic breast cancer that has relapsed after responding to first-line treatment.

E. Allogeneic stem cell transplantation, with or without HDC, is covered in the treatment of the following disease processes when either a related or unrelated donor is used:

1. Aplastic anemia

2. Acute lymphocytic or nonlymphocytic leukemias; chronic myelogenous leukemia (CML); or preleukemic syndromes. Treatment with unirradiated donor lymphocytes (buffy coat) is covered for CML patients who relapse following their first or subsequent course of HDC with allogeneic BMT. The medical record must document that the patient:

a. Is in relapse following an adequate trial of HDC with allogeneic BMT of CML; and

b. Qualified (or would have qualified) for authorization for HDC with allogeneic BMT according to the provisions set forth in this policy.

3. Severe combined immunodeficiency; e.g., adenosine deaminase deficiency and idiopathic deficiencies. Partially matched-related donor stem cell transplantation (without regard for the number of antigens mismatched in determining histocompatibility) in the treatment of Bare Lymphocyte Syndrome.

a. Partially matched-related donor stem cell transportation (without regard for the number of mismatched antigens) in the treatment of Bare Lymphocyte Syndrome.

b. Unrelated donor and/or related donor (without regard for mismatched antigens) with or without T cell lymphocyte depletion in the treatment of familial erythrophagocytic lymphohistiocytosis, (FEL; generalized lymphohistiocytic infiltration; familial lymphohistiocytosis; familial reticuloendotheliosis; familial hemophagocytic lymphohistiocytosis; FHL) for patients whose medical records document failure of conventional therapy (etoposide; corticosteroids; intrathecal methotrexate; and cranial irradiation).

c. Partially matched-related donor stem cell transplantation (without regard for the number of mismatched antigens) in the treatment of X-linked severe combined immunodeficiency syndrome (X-Linked SCID).

4. Wiskott-Aldrich syndrome

5. Infantile malignant osteopetrosis (Albers-Schonberg syndrome or marble bone disease)

6. Thalassemia major

7. Intermediate and high grade lymphoma with bone marrow involvement

8. Myeloproliferative/dysplastic syndromes

9. Congenital mucopolysaccharidoses

10. Congenital amegakaryocytic thrombocytopenia

11. Metachromatic leukodystrophy

12. Sickle cell disease

F. Review of WHMC Denials for allogeneic transplantation.

1. If the initial medical review from WHMC results in a denial of an STSF NAS or authorization, and the beneficiary resides in a fiscal intermediary region, the patient or provider is offered further review rights by the TRICARE Medical Director.

2. If the beneficiary resides in a Managed Care Support (MCS) region, the patient or provider is offered further review rights in accordance with the TRICARE contractual requirements.

3. A denial of benefits issued by WHMC is not an initial determination as defined in DoD 6010.8-R, and is; therefore, not appealable through the TRICARE/CHAMPUS appeal process.

4. If the WHMC denial of benefits is overturned by the appropriate preauthorizing authority as outlined in paragraph A. above, written direction shall be provided to WHMC to issue appropriate authorization letter(s). Any written determination by the appropriate preauthorizing authority is considered to be an initial determination as defined in DoD 6010.8-R. In any case when the initial determination is adverse to the beneficiary or participating provider, the notice shall include a statement of the beneficiary's or provider's right to appeal the determination. The procedure for filing for an appeal also shall be explained.

5. WHMC does not provide authorizations for HDC with ABMT nor HDC with PSCT.

G. In those allogeneic stem cell transplantation cases in which it has been established that a related donor is not possible, and when the only alternative is an unrelated donor, TRICARE/CHAMPUS benefits may be extended only under the following conditions:

1. The patient must use the National Marrow Donor Program (NMDP) for donor searches. (The NMDP (1-800-654-1247) is located in Minneapolis, Minnesota, and is available to anyone needing assistance in locating a suitable donor for unrelated allogeneic bone marrow transplantation). Donor searches through foreign registries must first be initiated or coordinated through NMDP. Prior to using NMDP services, authorization must be obtained through Wilford Hall Medical Center (WHMC).

2. Donor matching must meet the criteria established by the NMDP for identical and mismatched typing (refer to paragraph H. under Policy).

3. Requests for a donor search must be initiated and coordinated through the NMDP, and the transplant must be performed at one of its NMDP certified centers.

4. TRICARE/CHAMPUS will reimburse costs for donor searches only when the search has been initiated and coordinated by the NMDP.

a. Charges for donor searches must be fully itemized and billed by the transplant center.

b. Costs for donor searches will be cost-shared in accordance with TRICARE/CHAMPUS established reimbursement guidelines for outpatient diagnostic testing.

c. Donor search costs may be billed at any time. There is no limit on how many searches a transplant center may request from the search printout.

H. Histocompatibility criteria: In cases where related donor matches are not perfect (e.g., the histocompatibility is less than an identical antigen match) the same criteria and standards for typing mismatched unrelated donors must be used.

1. For the purposes of the NMDP and TRICARE/CHAMPUS coverage, the greatest degree of incompatibility allowed between donor or recipient (for either related or unrelated donors) is a single antigen mismatch at the A, B, or Dr. locus except for:

a. Patients 18 years or younger with undifferentiated leukemia or chronic myelogenous leukemia (CML) where a 2 antigen mismatch is allowed for related donors; and

b. Patients aged 20 years or younger with aplastic anemia who have granulocyte levels below 200 per microliter where a 2 antigen mismatch is allowed for related donors; and

c. Patients with acute myelogenous leukemia (AML) of the M7 type where a 2 antigen mismatch is allowed for related donors.

2. Donor searches accomplished through foreign registries must meet the same typing criteria as established by the NMDP (refer to paragraph G.4. above).

3. DNA-HLA typing to determine histocompatibility.

I. Benefits will not be allowed for stem cell harvesting and/or cryopreservation until the stem cell reinfusion has been completed. In the event that the patient expires prior to the stem cell reinfusion being completed, benefits for the harvesting may be allowed.

J. TRICARE/CHAMPUS benefits are allowed for Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

K. TRICARE/CHAMPUS benefits may be allowed for DNA-HLA tissue typing in determining histocompatibility.

L. Charges for stem cell preparation and storage shall be billed through the transplantation facility in the name of the TRICARE/CHAMPUS patient.

POLICY CONSIDERATIONS

A. Claims for services and supplies related to the HDC and transplant for beneficiaries under the age of 18 will be reimbursed based on billed charges. Claims for HDC and transplant for adult patients, 18 years and older, will be reimbursed under the DRG payment system. Outpatient institutional facility charges will be paid as billed. Professional services are reimbursed under the CHAMPUS Maximum Allowable Charge Methodology. (See Chapter 3, Section 1.5.)

B. Transportation of the patient by air ambulance may be cost-shared when determined to be medically necessary. Benefits for advanced life support air ambulance (to include attendant) may be preauthorized by the appropriate preauthorizing authority on an individual case basis in conjunction with the preauthorization for the services themselves. See Chapter 7, Section 2.1.

C. In those cases where the beneficiary fails to obtain preauthorization, TRICARE/CHAMPUS benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority as outlined in paragraph A. and paragraph B. under Policy is responsible for determining if the patient meets the coverage criteria as listed in paragraph E. and paragraph F. under Policy, above. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and HCF authorization for HDC with ABMT or PSCT will be reimbursed only under Point of Service rules.

D. For beneficiaries who reside in TRICARE regions, the issuance of a Nonavailability Statement (NAS) for other than allogeneic bone marrow transplantation shall be in accordance with direction of the Lead Agent. For beneficiaries residing in fiscal intermediary regions, an NAS is required for HDC with ABMT or PSCT. For admissions prior to October 1, 1997, an NAS is not required for HDC with allogeneic transplantation, and the referral from WHMC takes the place of an NAS for beneficiaries residing within an MTF catchment area. For admissions on or after October 1, 1997, an STSF NAS is required for allogeneic bone marrow transplantation (see paragraph B. under POLICY).

EXCLUSIONS

TRICARE/CHAMPUS benefits will not be paid for:

A. HDC with ABMT or PSCT or HDC with allogeneic BMT if the patient has a concurrent condition (other existing illness) that would jeopardize the achievement of successful transplantation.

B. HDC with or without ABMT, HDC with or without PSCT, or HDC with or without allogeneic BMT if not specifically listed as covered in paragraph G. and paragraph H. under Policy above. For example, since ovarian cancer is not specifically listed as a covered indication for HDC with ABMT or PSCT, TRICARE/CHAMPUS benefits are excluded. This is not to imply that exclusions for HDC/ABMT or PSCT are limited solely to the exclusions for ovarian carcinomas.

C. In vitro stem cell processing (purging) as this procedure is considered investigational. See Chapter 8, Section 14.1, for guidance regarding the handling of claims for services or supplies related to investigational procedures.

D. Expenses waived by the transplant center (i.e., beneficiary/sponsor not financially liable).

E. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant, or research program; investigational procedure).

F. Administration of an experimental or investigational immunosuppressant drug that is not FDA approved. Refer to Chapter 7, Section 7.3 for TRICARE/CHAMPUS policy requirements for immunosuppression therapy.

G. Pre- or post-transplant nonmedical expenses (i.e., out-of-hospital living expenses, to include, hotel, meals, privately owned vehicle for the beneficiary or family members).

H. Transportation of a donor.

I. HDC with ABMT or PSCT is not a TRICARE/CHAMPUS benefit for treatment of low grade non-Hodgkin's lymphoma.

J. Umbilical cord blood transplantation therapy as this procedure is considered investigational. Refer to TRICARE/CHAMPUS Policy Manual, Chapter 8, Section 14.1 for guidance regarding the handling of claims for services or supplies related to investigational procedures.

EXCEPTIONS

A. If the patient otherwise meets the coverage criteria for HDC with ABMT as listed in paragraph E.1. (under Policy, above), harvesting of the required stem cells by apheresis from peripheral blood (i.e., PSCT) rather than bone marrow can be allowed.

B. A demonstration project is being conducted wherein the DoD will participate in cancer treatment clinical trials under approved National Cancer Institute (NCI) protocols to include high dose chemotherapy with stem cell rescue (HDC/SCR). Refer to the COM-FI Part Two, Chapter 20, Section II.D. and OPM Part Two, Chapter 20, Section II.D. for additional information regarding the demonstration project.

EFFECTIVE DATE

A. May 1, 1987, for HDC with ABMT or PSCT for Hodgkin's disease, non-Hodgkin's lymphoma and neuroblastoma.

B. November 1, 1987, for HDC with ABMT or PSCT for acute lymphocytic and nonlymphocytic leukemias.

C. November 1, 1983, for HDC with allogeneic bone marrow transplants using related donors.

D. July 1, 1989, for HDC with allogeneic bone marrow transplants using unrelated donors.

E. July 11, 1996, for HDC with ABMT for multiple myeloma.

F. October 1, 1995, for HDC with ABMT for metastatic breast cancer.

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